

Appl. No.10/665,537

Amendment dated July 2, 2004

Reply to Office Action of March 2, 2004

Attorney Ref. No.: 082137-0306009

## **II. REMARKS**

### **Preliminary Remarks:**

The title of the application is amended to correspond more closely to the subject matter of the claims.

Claim 14 and 17 are amended by removing references to "a prophylactically effective amount" and an "extract." Claim 20 is amended to be directed to the method of protecting a human against human PV infection of claim 17 wherein the vaccine that is administered comprises a formalin-treated L1 protein of a human papillomavirus. Use of vaccine comprising formalin-treated L1 protein to induce protective immunity in a canine model system that is predictive of efficacy of the claimed invention in humans is described on page 50 (Example 4). New claims 21 and 22 are directed to a vaccine composition comprising formalin-treated human papillomavirus L1 protein of an extract of cells of a papillomavirus-induced tumor, and to a method for conferring protective immunity to a human comprising administering such a vaccine composition. New claims 23 and 24 are directed to a vaccine composition comprising formalin-treated human papillomavirus L1 protein of an extract of cells containing and expressing recombinant DNA encoding said human papillomavirus L1 protein. Support for new claims 21-14 is found in the specification, e.g., in Examples 4-6.

### **Patentability Remarks:**

#### **35 U.S.C. §112, Second Paragraph**

Claims 14, 16, 17, and 20 were rejected under 35 U.S.C. §112, Second Paragraph, as being indefinite because the concise meaning of the terms "effective amount" and "extract" is not clear.

As noted above, references to "a prophylactically effective amount" and an "extract" have been deleted from claims 14 and 17. Withdrawal of the rejection under 35 U.S.C. §112, Second Paragraph, is respectfully requested.

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35 U.S.C. §112, First Paragraph

Claims 14, 16, 17, and 20 were rejected under 35 U.S.C. §112, First Paragraph. The official action acknowledges that the specification is enabling for a composition of formalin-inactivated papillomavirus L1 protein, and for the utilization of such a composition as a therapeutic vaccine. However, the official action alleges that the specification does not enable one of skill in the art to use the disclosed human papillomavirus composition and method to confer prophylactic protection against all types of human papillomaviruses.

As amended, the language of present claims 14, 16, 17, and 20 is nearly the same as the language proposed by the examiner for putting the claims of related application 09/134,377, now U.S. Patent No. 6,485,728 B2, into condition for allowance. The applicants respectfully submit that, like the claims of U.S. Patent No. 6,485,728 B2, the present claims also satisfy the criteria for patentability under U.S. patent law. As noted above, support for new claims 21-24 is found in the specification, e.g., in Examples 4-6. Examples 4 and 5 (pages 49-52) describe a vaccine composition comprising formalin-treated human papillomavirus L1 protein of an extract of cells of a papillomavirus-induced tumor, and a method for successfully conferring protective immunity in a canine model comprising administering such a vaccine composition. Persons of skill in the art would reasonably expect the disclosed canine model system to be predictive of efficacy of the claimed vaccine in humans. Using L1 protein produced by expression of recombinant DNA in cells *in vitro*, Example 6 demonstrates that formalin-treated L1 protein of the extract alone is sufficient to confer the protective immunity (pages 52-55). As discussed in the specification, the papillomavirus L1 capsid protein is highly conserved (e.g., see p. 36, lines 15-25), and persons of skill in the art would reasonably expect the disclosed methods for preparing and using a vaccine comprising L1 capsid protein to operate successfully for the human papillomaviruses of the claims without the necessity for undue experimentation.

Double Patenting

Claims 14, 16, 17, and 20 were rejected for obviousness double-patenting in view of the claims of co-pending U.S. Application No. 09/134,377. The claims of the conflicting application were allowed and the application issued as U.S. Patent No. 6,485,728 B2 on November 26, 2002. Attached hereto is a terminal disclaimer that disclaims the portion of

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the term of a patent that issues from the present application that extends beyond the term of U.S. Patent No. 6,485,728 B2.

### Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,  
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